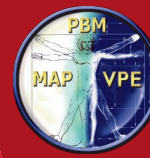




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○ ISSUE 5 | ○ VOLUME 3 | ○ MAY 2013

Medication *safety in seconds*

A MONTHLY PUBLICATION FROM VA MEDSAFE:
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER

Helping to achieve safe medication use

SAMSCA (TOLVAPTAN) AND LIVER INJURY

On April 30, 2013, FDA released a Drug Safety Communication on the use of tolvaptan. To reduce the risk of serious liver injury that could potentially result in liver transplant or death, FDA recommends that tolvaptan should not be used for durations longer than 30 days or in patients with underlying liver disease.

The updated recommendations are based on observations from recent, large clinical trials evaluating the use of tolvaptan in patients with autosomal dominant polycystic kidney disease (ADPKD), an off-label indication. During the trial of about 1,400 patients, three patients treated with tolvaptan developed serious liver injury considered probably or highly likely to be caused by tolvaptan. In addition, more patients in the tolvaptan group experienced significant transaminase elevations (4.4% vs. 1%) compared to placebo. The earliest case of severe liver injury occurred three months after initiation of tolvaptan.



Clinical trials that evaluated the use of tolvaptan for the FDA approved indication of the treatment of clinically significant hypervolemic or euvolemic hyponatremia did not reveal a signal of hepatotoxicity when studied for a duration of about 30 days. The maximum recommended dose for the FDA approved indication is 60 mg daily, which is lower than the 120 mg daily maximum dose allowed in the clinical trials studying tolvaptan in patients with ADPKD.

Summary of recommendations and changes in labeling:

- Maximum duration of tolvaptan treatment should not

(continued on page 3)



NEWS YOU CAN USE

FROM THE VA NATIONAL PBM: BULLETINS, COMMUNICATIONS, & RECALLS

- Prevnar 13 and Pneumovax 23: Medication Errors and Appropriate Use – 04-10-2013 - [National PBM Bulletin](#)



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NEWS YOU CAN USE

FROM THE FOOD AND DRUG ADMINISTRATION (FDA)

VASOPRESSIN ANTAGONIST

[FDA limits duration and usage of Samsca \(tolvaptan\) due to possible liver injury leading to organ transplant or death](#)

4/30/2013

FDA recommends not using Samsca (tolvaptan) for longer than 30 days and in patients with underlying liver disease because it can cause liver injury, potentially requiring liver transplant or resulting in death. Samsca (tolvaptan) is a selective vasopressin V2-receptor antagonist indicated for the treatment of clinically significant and symptomatic hypervolemic and euvoletic hyponatremia resistant to correction in patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH). See pages 1 and 3 for detailed information.

ANTICONVULSANTS

[Anti-seizure drug Potiga \(ezogabine\) linked to retinal abnormalities and blue skin discoloration](#)

4/26/2013

The anti-seizure medication Potiga (ezogabine) can cause pigment changes in the skin and retina. Skin discoloration has manifested as a bluish hue occurring on the face, lips, sclera, eyelids, legs, and in nail beds of the fingers and toes. Pigment changes in the retina may lead to serious eye disease with a possible loss of vision. The skin discoloration and retinal abnormalities occurred in patients enrolled in Potiga (ezogabine) clinical trials as well as 2 ongoing extension studies and have appeared after long treatment intervals (mean = 4 years; median = 4 years; range 1-7 years). As of April 2013, 38 out of approximately 605 patients developed skin discoloration, but all patients have not yet undergone examination. Of 89 patients in the ongoing studies, 36 had eye examinations, of which 11 had abnormal retinal findings; however, these patients did not have any baseline visual acuity assessment. FDA does not know whether these changes are reversible and is working with the manufacturer to obtain more information. FDA recommends:

- *All patients taking Potiga should have a baseline eye exam and periodic eye exams that should include visual acuity testing and dilated fundus photography, and may include fluorescein angiograms (FA), ocular coherence tomography (OCT), perimetry, and electroretinograms (ERG). The latency of retinal abnormalities after treatment initiation is unknown, although all known cases of retinal abnormalities were reported after an exposure to Potiga of at least three years.*
- *If a patient develops skin discoloration, serious consideration should be given to changing to an alternate medication.*
- *Patients should not stop taking Potiga or any anti-seizure medication without talking to their health care professional, as stopping anti-seizure treatment suddenly can precipitate withdrawal seizures, a serious and life-threatening medical problem.*

Getting the most from our safety surveillance

LOOK-ALIKE SOUND-ALIKE MEDICATION NAME PAIRS WITHIN THE VA SYSTEM

Similar drug names account for approximately 15% of all reports to the USP Medication Errors Reporting program. Such errors may take place anywhere in the drug delivery process from prescribing (written, oral, or computer entry), to progress note documentation, to medication dispensing. This can be a source of potential harm to the patient if the wrong drug is administered.

Each year VAMedSAFE queries VISN Pharmacy Executives on reports of look-alike/sound-alike (LA/SA) close-calls and mix-ups at the local VA level on an annual basis and compiles a list of confusing name pairs from a system-wide perspective. Results are available in two formats: [VA Reported LASA Drug Names in 2012](#) and [Cumulative VA LASA list 2012](#) (which

contains name pairs reported in previous years). These lists can serve as tools to help sites evaluate real and potential errors from those identified LA/SA pairs for action and follow-up, if necessary. Other resources available for identifying potentially confusing LA/SA name pairs includes:

- ISMP Confused Drug Name List - <http://www.ismp.org/Tools/confuseddrugnames.pdf>
- Lexi-Comp Online – Medication Safety Issues - <http://online.lexi.com/crlsql/servlet/crlonline>
- First DataBank TallMan Lettering List (VA National Drug File subscription).

VA MedSAFE encourages healthcare staff to continue to participate in submitting local LA/SA information in order to:



(continued on page 3)

Getting the most from our safety surveillance

LOOK-ALIKE SOUND-ALIKE MEDICATION NAME PAIRS WITHIN THE VA SYSTEM

(continued from page 2)

1. Educate health care providers on newly reported LA/SA potentials and close-calls;
2. Implement policies that minimize drug name confusion, such as:
 - a. Developing alternative stocking methods for LA/SA drug pairs other than alphabetically by name.
 - b. Placing auxiliary reminder labels on containers of identified LA/SA drugs pairs to alert all personnel involved in the dispensing process.
 - c. When placing verbal/telephone orders, prescriber must provide correct spelling of drug name, and person receiving the order must repeat the drug name and dose ordered.
 - d. When dispensing a drug with LA/SA potential, the practitioner should inquire if the drug is a routine or new medication. In the event the patient does not recognize the drug, the prescription should be withheld until confirmed with the progress note or the prescriber.
3. Design safeguards and alerts to reduce the probability of

drug name confusion in the prescription order entry and dispensing process.

If you have received reports of LA/SA potential or actual mix-ups in the past year, please send them to Muriel.Burk@va.gov, and please include the following information, if possible:

- Description of the event;
- Point at which error occurred (e.g. prescribing, selecting, stocking, dispensing, administration, etc.);
- Point at which error was discovered (same as above plus consumer/patient reported);
- Whether patient actually ingested the wrong drug;
- Outcome of the patient and if medical resources were needed to manage;
- Appropriate personnel notified at facility;
- If facility conducted an RCA or case review; and
- Follow-up actions implemented.

REFERENCE:

Hampton T. Similar Drug Names a Risky Prescription. *JAMA*. 2004;291(16):1948-1949.

Helping to achieve safe medication use

SAMSCA (TOLVAPTAN) AND LIVER INJURY

(continued from page 1)

- exceed 30 days to minimize the risk of liver injury.
- Discontinue tolvaptan in patients with symptoms of liver injury.
- Tolvaptan is no longer indicated for use in patients with hyponatremia and underlying liver disease, including cirrhosis, because of potential impairment in the ability to recover from liver injury.
- Summary of data provided on liver injury was observed in clinical trials of patients with ADPKD.

REFERENCE:

FDA Safety Communication: FDA limits duration and usage of Samsca (tolvaptan) due to possible liver injury leading to organ transplant or death. <http://www.fda.gov/Drugs/DrugSafety/ucm350062.htm> (Accessed May 1, 2013).

Contributed by:

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